

REMARKS

Applicants have now had an opportunity to carefully consider the Examiner's comments set forth in the Office Action of November 25, 2008.

Reconsideration of the Application is requested.

Claims 1-9 are pending in the application.

Claims 1 and 4-6 have been amended.

New claims 7-9 are added.

The Office Action

Drawing Objections

The drawings were objected to because FIGURE 7 is said to be dark and the scale cannot be determined. Applicants submit herewith a clean copy of page 4 of the drawings in which FIGURE 7 has been replaced with a clean copy of the photograph and a typographical error in FIGURE 8 has been corrected. In particular "intesity" is replaced with "intensity."

Claim Objections

Claims 4-6 were objected to as being improper dependent claims. Claim 4 has been placed in independent form and claims 5 and 6 amended to depend from claim 4. Accordingly, it is respectfully requested that the objection be withdrawn.

§102(b) Rejections

Claims 1-6 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,952,010 to Constantz.

For the reasons outlined below, it is submitted that the claims are in condition for allowance.

Claim 1 recites a method of producing a bone substitute material in the form of a block predominantly composed of carbonate apatite. The method includes forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution. The calcium compound block contains substantially no powders. At least one of the calcium compound block and the phosphate solution contains a carbonate group.

Constantz discloses paste compositions capable of setting into carbonated apatite (title). The compositions can be prepared such that they are flowable, moldable, and capable of hardening in situ (summary). The Examiner refers to col. 5, lines 28-52 of Constantz, which states:

In selecting the calcium source, particularly where the calcium source serves a dual role of providing calcium and acts in a neutralizing capacity, one must consider that the desired final product will depend on the relative ratios of calcium and phosphate. Calcium sources will generally include counterions such as carbonate, phosphate or the like. Of particular interest are dual sources of calcium phosphate and phosphate such as tetracalcium phosphate (C_4P) or tricalcium phosphate (C_3P). Tetracalcium phosphate or tricalcium phosphate may typically be present in the mixture at from about 0 to 70 weight percent, more usually from about 0 to 40 weight percent, and preferably from about 2 to 18 weight percent of dry weight of the dry components of the mixture. With calcium carbonate present to neutralize the acid and to serve as a source of calcium and carbonate, the reaction will result in relatively little temperature rise; however, there is substantial evolution of gas which must be released during mixing. Calcium carbonate will be present in the mixture from about 2 to 70 weight percent, more usually from about 2 to 40 weight percent, and preferably from about 2 to 18 weight percent of dry weight of the dry components of the mixture. Calcium hydroxide may also be present in the mixture from about 0 to 40 wt. %, more usually from about 2 to 25 wt. %, and optimally from about 2 to 20 wt. %.

This paragraph refers simply to a mixture of dry components. There is no suggestion that the dry components form a block. Further, it is hard to see how the "dahlite or francolite-like products" of Constantz could be readily formed by "combining the wet and dry reactants to provide a substantially uniform mixture, shaping the mixture as appropriate" (Constantz, col. 4, line 49-53), if the dry reactants were in the form of "a block predominantly composed of carbonate apatite," as claimed.

The Examiner further refers to Constantz at col. 6, lines 1-11, which states:

The various dry components may be combined prior to the addition of the wet components. Mixing will be used to combine the ingredients and can be used to regulate the extent of the inter-ingredient reactions. Any or all of the dry ingredients may be added prior to the initiation of mixing or prior to the completion of mechanical mixing. Methods of mixing can include ball milling, Brabender mixing, rolling between one or more rollers and a flexible container, or the like. Preferably, mixing will be thorough and will occur for a relatively short time or until a uniform dispersal of ingredients is obtained.

Once again, there is no suggestion in this paragraph of "a foam block of calcium compound," as the Examiner asserts. Rather, it is clear that the dry components are mixed by ball milling, rolling or the like, which would clearly not result in a foam block. Rather, such a mixing process will inevitably result in the formation of a powder, even if the dry ingredients do not start in highly powdered form.

The Examiner asserts that the uniform dispersion produced has substantially no powder. Applicants respectfully submit that there is no suggestion in this paragraph that anything other than a powder is formed. As noted in the present specification at page 7, lines 7-10, "substantially no powder" refers to a block in which powders with a diameter of 20 μ m or smaller are in an amount of less than 1% by weight. Applicant, pursuant to MPEP 2144.03, calls upon the Examiner to withdraw the assertion that the dispersion of Constantz contains substantially no powder or provide evidence in support of the statement.

Further, the dry ingredients of Constantz are mixed with a liquid to form a paste. There is no suggestion as to how a paste, which passes through a needle in the range of about 10-18 gauge, preferably about 14-16 gauge (see, Constantz, col. 6, lines 30-35), could be formed unless the dry ingredients were in the form of a fine powder.

New claim 7 recites that the contacting of the block of calcium compound with the phosphate-containing solution comprises immersing the block in the phosphate-containing solution. Support for new claim 7 is to be found in the specification at page 13, third paragraph. Such an immersion is not suggested in Constantz. Rather, dry ingredients are simply mixed with a lubricant to form a paste.

New claim 8 recites that the porous block has an average pore diameter in a

range of 50-1000 μ m. Support for new claim 8 is to be found in the specification at page 13, second paragraph. Constantz makes no suggestion of a porous block with an average pore diameter in a range of 50-1000 μ m. Rather Constantz uses a finely comminuted starting material generated by ball milling, rolling, or the like.

Accordingly, it is submitted that claim 1, and claims 2, 3, 7, and 8 dependent therefrom, distinguish patentably and unobviously over Constantz.

Claim 4 recites a bone substitute material which is produced by method which includes forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution, wherein said calcium compound block contains substantially no powders, wherein at least one of said calcium compound block and said phosphate solution contains a carbonate group, and wherein the method does not include any sintering step, and wherein the bone substitute material is predominantly composed of carbonate apatite with carbonate group content of 0.5% or more by weight.

The product of Constantz is a paste which may be hardened. The present product distinguishes from that of Constantz in that the resulting carbonate apatite block contains substantially no powder. There is no suggestion that the hardened paste of Constantz will contain substantially no powder. Rather, Applicants submit that crystalline inflammation may result from the powders liberated from the paste composition of Constantz through friction. In other words, the absence of powder in the claimed material is advantageous.

New **claim 9** recites a method of producing a bone substitute material predominantly composed of carbonate apatite. The method includes providing a porous body formed of a calcium compound, the body containing substantially no powders and having an average pore diameter in a range of 50-1000 μ m. The porous body is contacted with a phosphate-containing solution. At least one of the porous body and phosphate solution contains a carbonate group, whereby the porous body is predominantly composed of carbonate apatite.

Support for new claim 9 is to be found in original claim 1 and in the specification at page 13, second and third paragraphs.

Constantz makes no suggestion of forming a bone substitute material from a body having an average pore diameter in a range of 50-1000 μ m, which after contacting

with a phosphate solution, is predominantly composed of carbonate apatite. Accordingly, it is submitted that claim 10 distinguishes over the Constantz reference.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1-9) are now in condition for allowance.

☒ Remaining Claims, as delineated below:

(1) FOR	(2) CLAIMS REMAINING AFTER AMENDMENT LESS HIGHEST NUMBER PREVIOUSLY PAID FOR		(3) NUMBER EXTRA
TOTAL CLAIMS	9	- 20 =	0
INDEPENDENT CLAIMS	3	- 3 =	0

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is hereby authorized to call the undersigned, at Telephone Number (216) 363-9000.

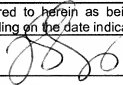
Respectfully submitted,

Fay Sharpe LLP

March 25, 2009

Date


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